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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,518

03/26/2004

Thomas H. Barrows

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EXAMINER

WARE, DEBORAH K

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/810,518	<b>Applicant(s)</b> BARROWS ET AL.	
	<b>Examiner</b> DEBBIE K. WARE	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-54 is/are pending in the application.
- 4a) Of the above claim(s) 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-48 and 51-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

**DETAILED ACTION**

Claims 32-54 are pending in the instant case.

***Election/Restrictions***

Claims 49-50 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 19, 2006.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment submission filed on December 28, 2007, has been entered.

***Miscellaneous Papers***

Also the Power of Attorney and Assignee showing of ownership per 37 CFR 3.73(b) and change of address, all received on January 18, 2008, have been received.

Further, the Affidavits submitted under Rule 130, 131 or 132 have been received.

***Declaration Under 37 CFR 1.132***

The declaration by Thomas H. Barrows is acknowledged and has been considered as follows below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 is rendered vague and indefinite for the recitation of “ bioabsorbable material” because it is unclear what the material is per se, and how does this material differ from a modifier? Does the material afford the filament its bioabsorbability or does it merely make the lumen bioabsorbable in addition to the filament comprising the lumen. The metes and bounds of claim 44 can not be determined.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-48 and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Barrows (US 7,198,641) filed July 14, 2003 in view of newly cited Bell et al (US 5,891,558), and previously cited Romero-Ortega et al and Simpson et al, these latter two both cited of record.

Claims are drawn to a graft comprising a bioabsorbable filament having a central lumen, and cells capable of initiating hair follicle neogenesis comprising epidermal cells and dermal cells disposed within the lumen.

Barrows teaches a graft comprising a scaffold component which is a hollow filament comprised of one or more bioabsorbable polymers and cells from hair follicles useful for initiating hair follicle neogenesis. Note the abstract and further note column 5, lines 14-50 and column 6, lines 20-27. The cells can be dermal papilla as well, note column 4, line 25. Also the cells can be follicle progenitor cells, note column 4, line 21.

Bell et al teach a graft comprising epidermal and dermal cells from different sources and growth factors. Note column 11, lines 10-15 and 34-40. Further, note column 1, lines 35-55.

Romero-Ortega et al teach a graft comprising a bioabsorbable filament having a central lumen and skin cells disposed within and adjacent to the lumen, in terms of a cell growth scaffold providing channels comprising extracellular matrix gel (see abstract and page 4, column 1 [0027], lines 4-5. Also note page 5, column 1, [0042], line 3 and column 2, [0053], lines 13-15. The skin includes epidermal cells and dermal cells. The

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lumen inherently has an interior wall because the skin cells are disposed within the channels comprising the lumen and adhere to the interior surface, note page 4, [0029], lines 1-4. Furthermore, the lumen is inherently smooth, porous, hydrophilic and porous because it is comprised of extracellular matrix gel which has all of these properties. In addition the gel is a well recognized bioabsorbable material which has attachment binding site moieties.

Simpson et al teach that cell attachment binding site moieties, such as Arg-Gly-Asp, known as the RGD site which is a peptide sequence present in many extracellular matrix materials, note page 7, [0079], lines 10-12, which serves as a binding site for cell adhesion.

The claims differ from Barrows in that a modifier and the presence of epidermal cells and lumen are not specifically disclosed by Barrows.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further include in the graft of Barrows, a modifier (i.e. growth factors) and epidermal cells as disclosed by Bell et al and Romero-Ortega et al and to further select a modifier from cell attachment binding site moieties from Arg-Gly-Asp, known as RGD site, as disclosed by Simpson et al; because one of ordinary skill would have been motivated to enhance cell growth using modifiers to initiate hair follicle neogenesis as disclosed by Barrows. Within the graft disclosed by Barrows cells are used that are capable of hair follicle neogenesis. To modify Barrows with the teachings of the secondary prior art references for the selection of modifiers to promote cell growth in a graft is clearly an obvious modification of the cited prior art. Furthermore, to

select epidermal cells with dermal cells in a graft is also well within the purview of an ordinary skilled artisan.

Barrows and Romero-Ortega et al clearly teach a bioabsorbable filament as being a well recognized component of a graft. Although Barrows does not specifically teach a lumen per se, the lumen is suggested by the teachings of Barrows since a hair follicle graft is made up of a hollow filament comprised of one or more bioabsorbable polymers, of which intrinsically define an interior lumen. The cells are clearly suggested, if not taught, by the cited prior art to be disposed within the lumen. Both cell types are disclosed to be from hair follicles, dermal papilla or dermal sheath, and epidermal cells are disclosed to be from skin, thus, the two cell types can be from different sources, as disclosed by the cited prior art.

Furthermore, to clump the dermal cells is clearly within the purview of an ordinary artisan and one of skill would have been able to isolate the dermal cells by clumping. The cells would have further been expected to adhere to the interior wall of the lumen or adjacent thereto. Also, the lumen would have been expected to be smooth, porous, hydrophilic and porous because it is comprised of extracellular matrix gel which has all of these properties. In addition the gel is a well recognized bioabsorbable material which has attachment binding site moieties. Also if one of skill would have desired the lumen to be hydrophobic, then one of ordinary skill in the art would have well within their purview the ability to select for a hydrophobic polymer material for the bioabsorbable filament. The filament of the cited prior art comprises a first end that is closed and the cells are concentrated therein.

Each of the claimed features are clearly disclosed or suggested by the cited prior art and one of ordinary skill in the art would have expected successful results for the combination of the materials disclosed by each of the cited references. In the absence of persuasive evidence to the contrary the claims are deemed *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed December 28, 2007, have been fully considered but they are not persuasive. The declaration presented by Thomas H. Barrows is respectfully acknowledged and deemed persuasive with respect to the application of the previous prior art over 35 USC 102(b). However, the declaration does not overcome the references in terms of their secondary teachings and because the scope of the claimed subject matter includes epithelial cells and the intended use of the graft as claimed is not necessarily given any patentable weight. Each of the claimed features are disclosed, or are at least suggested, by the newly cited prior art rejection. With respect to the rebuttal arguments regarding Romero-Ortega et al, the newly cited prior art clearly remedies any insufficiencies of the previously cited prior art. However, the rejection over 35 USC 102 has been removed and new rejection under 35 USC 103 has been set forth above to address the newly presented claims and the points raised by the declaration and the rebuttal remarks of December 28, 2007.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory



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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-48 and 51-54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 11/603,818. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims is the scope of the claimed subject matter, wherein the instant claims do not have a protectant and as part of the graft and the lumen of the bioabsorbable filament is centrally placed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims are drawn to a graft comprising a bioabsorbable filament and cells comprising epidermal and dermal cells disposed within a lumen of the filament.

The copending claims are drawn to a graft comprising epidermal cells and dermal cells and a bioabsorbable filament having an inner lumen and a protectant.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the instantly claimed graft because one of ordinary skill in the art would have been motivated by the copending claimed hair graft since the gelatin of the copending claims which serves as a protectant is bioabsorbable and hence the instantly claimed graft would have been expected to provide a hair graft much like the copending claimed hair graft. Hence, the only difference between the instant claims and the copending claims is scope and one of ordinary skill would have well within their level of skill the selection of a protectant which reads on a bioabsorbable material useful within the inner lumen of the filament as claimed herein.

Therefore, each of the instantly claimed features are recited and taught in the copending claims or are at least suggested by them. Thus, in the absence of persuasive evidence to the contrary the claims are clearly prima facie obvious over the copending claimed subject matter.

Claims 32-48 and 51-54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/562,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims is the scope of the claimed subject matter, wherein the instant claims do not specify progenitor cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are discussed above.

The copending claims are drawn to a hair graft comprising a tissue engineered skin having a tissue engineered epidermal layer, a tissue engineered dermal layer and hair follicle progenitor cells and scaffold, therefore.

The instant claims differ from the copending claims in that progenitor cells are not specifically recited in the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a graft as instantly claimed based upon the recited teachings of the copending claims of a tissue engineered skin having a tissue engineered epidermal layer, a tissue engineered dermal layer and hair follicle progenitor cells and scaffold, therefore, because a graft as instantly claimed comprises a filament and broadly defined epidermal and dermal cells disposed therein of which clearly reads on the copending hair graft. The copending hair graft teaches a scaffold which can be made up of a bioabsorbable filament as instantly claimed. The teaching of copending claims recite that the progenitor cells are comprised of dermal cells as instantly claimed herein. Clearly the claimed subject matter is at least suggested by the copending claims and one of skill would have been motivated to provide for a graft as instantly claimed. Each of the instantly claimed features are taught or suggested by the copending claims. Therefore, the claims are rendered prima facie obvious over these copending claims as well.

Claims 32-33, 43-44, 45 and 48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 7, 11, 12, and 13 of copending Application No. 11/107230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims is the scope of the claimed subject matter, wherein the instant claims do not specify a means per se, however they do not exclude a means wherein a graft can include a filamentary means.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are discussed above.

The copending claims are drawn to a filamentary means which comprises a filament comprising a solid core and a porous sheath that is bioabsorbable and coats at least a portion of the solid core, and cells from hair follicles and cell attachment molecules or cell binding site molecules.

The instant claims differ from the copending claims in that a filamentary means is not specifically recited in the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a graft as instantly claimed based upon the recited teachings of the copending claims of a filamentary means, because a graft as instantly claimed comprises a filament and broadly defined epidermal and dermal cells disposed therein of which clearly reads on the copending agent which is further comprised by a filamentary means of the copending claims. The copending filamentary

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means teaches the living cells are from hair follicles of which the instant claims are also derived from these hair follicles. Furthermore, the filamentary means can be made up of a bioabsorbable filament as instantly claimed. Clearly the claimed subject matter is at least suggested by the copending claims and one of skill would have been motivated to provide for a graft as instantly claimed. Each of the instantly claimed features are taught or suggested by the copending claims. Therefore, the claims are rendered prima facie obvious over these copending claims as well.

Claims 32-33, 43 and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,198,641. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims is the scope of the claimed subject matter.

The claims are drawn to a graft comprising a bioabsorbable filament and cells capable of initiating hair follicle neogenesis comprising epidermal and dermal hair follicle cells.

The patented claim is drawn to a graft comprising a bioabsorbable polymer and cells capable of initiating hair follicle neogenesis of which the cells are comprised of hair follicle progenitor cells.

The claims differ from the patented claim in that the cells are epidermal and dermal hair follicle cells and the filament is made up of a polymer.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a graft comprising bioabsorbable filament

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made of bioabsorbable polymers and cells capable of initiating hair follicle neogenesis comprising epidermal and dermal hair follicle cells because the patented claim teaches that polymers are bioabsorbable and the progenitor cells are well known to differentiate to any desired cell type under a given set of cultural conditions. Thus, for one of skill to provide for the cell culture conditions for which to select for the differentiation of the progenitor cells into epidermal cells and dermal cells in which to combine them with a bioabsorbable filament is an obvious modification. The patented claim clearly suggests that a graft can be formed of a bioabsorbable filament and hair follicle cells. Thus, one of skill would have expected successful results.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/  
Deborah K. Ware  
March 29, 2008

/David M. Naff/  
Primary Examiner, Art Unit 1657